Remarks

In the outstanding Official Action, the Examiner:

(1) indicated that claims 16-18 and 20 are directed to an invention that is independent or distinct from the invention originally claimed, and are therefore withdrawn from further consideration as being directed to a non-elected invention;

(2) rejected claims 1, 3-7, 11-15 and 19 under 35 USC 112, first paragraph, as failing to comply with the written description requirement, raising issue in claim 1 with the terms "easy flow under the shear forces imparted by a syringe such that the composition may be instilled into, and withdrawn from, a hemodialysis catheter using such a conventional medical syringe" and "the composition remains in the lumen substantially without leakage", and raising issue in claim 19 with the term "colloidal suspension";

(3) rejected claims 1, 3-5, 11, 13-15 and 19 under 35 USC 102(b) as being anticipated by Luissi et al. (U.S. Patent No. 4,587,284) ("Luissi");

(4) rejected claims 1, 3-4, 6, 13-15 and 19 under 35 USC 102(b) as being anticipated by Marchant et al. (U.S. Patent No. 6,297,337) ("Marchant");

(5) rejected claims 1, 3-5, 11-15 and 19 under 35 USC 102(b) as being anticipated by Wokalek et al. (U.S. Patent No. 4,905,700) ("Wokalek");

(6) rejected claims 1, 3, 7, 11-15 and 19 under 35 USC 102(e) as being anticipated by Young et al. (U.S. Patent Publication No. 2003/0180347) ("Young"); and

(7) rejected claims 1, 3-5 and 19 under 35 USC 102(b) as being anticipated by Pfirrmann et al. (International Publication No. WO 94/03174) ("Pfirrmann").

With respect to Item 1 above, Applicant believes that no response is necessary. However, Applicant notes that it intends to pursue the subject matter of these claims in related applications.

With respect to Item 2 above, Applicant respectfully disagrees with the Examiner's rejections under 35 USC 112, however, in order to expedite this matter, Applicant has now amended claims 1 and 19 so as to more clearly define the present invention.

Specifically, with respect to claim 1, Applicant has amended the previous language "easy flow under the shear forces imparted by a syringe such that the composition may be instilled into, and withdrawn from, a hemodialysis catheter using such a conventional

medical syringe" so that it now reads "free flow upon the application of a threshold level force imparted by a conventional medical syringe such that the composition may be instilled into, and withdrawn from, a hemodialysis catheter using such a conventional medical syringe". Support for this is provided at numerous locations within the specification, e.g., at page 16, lines 5-7.

Also with respect to claim 1, Applicant has amended the previous language "the composition remains in the lumen substantially without leakage" so that it now reads "the composition remains in the lumen". Support for this is provided at numerous locations within the specification, e.g., at page 15, lines 10-11, at page 23, lines 30-32, etc.

With respect to claim 19, Applicant has amended the previous language "colloidal suspension" so that it now reads "colloidal dispersion". Support for this is provided within the specification, e.g., at page 15, line 23.

Accordingly, Applicant believes that the issues raised by the Examiner in claims 1 and 19 under 35 USC 112 have now been rendered moot by the present amendments, and reconsideration on this point is respectfully requested.

In response to Items 3 through 7 above, Applicant respectfully traverses the Examiner and respectfully requests reconsideration for the reasons which follow.

Claim 1 has now been amended to call for a composition comprising a thixotropic gel and an antimicrobial agent contained in the thixotropic gel. Furthermore, the amended claim now makes it clear that the thixotropic gel is characterized by:

(i) free flow upon the application of a threshold level force imparted by a conventional medical syringe such that the composition may be instilled into, and withdrawn from, a hemodialysis catheter using such a conventional medical syringe;

(ii) sufficient cohesiveness such that, when the composition is moved through the lumen of a hemodialysis catheter using a conventional medical syringe, the composition advances through the lumen as a cohesive rod-shaped mass; and

(iii) when the composition is disposed within the lumen of a hemodialysis catheter which is installed in the vascular system of a patient, the composition remains in the lumen. In addition, this claim also calls for the thixotropic gel to be biocompatible and biodegradable in blood.

Applicant has reviewed the cited references. None of the references relate to a thixotropic gel having the characteristics

called for in claim 1 and, accordingly, none of the references teaches a composition similar to Applicant's invention as now claimed.

Luissi, Wokalek, Young and Pfirrmann all fail to disclose a thixotropic gel. This omission may not be significant given the applications intended by Luissi, Wokalek, Young and Pfirrmann, however, it is critical when one considers the application intended by Applicant, i.e., a catheter lock. More particularly, it is the thixotropic nature of Applicant's gel which makes it practical to use a gel in a hemodialysis catheter in accordance with current industry practice, e.g., instilling and removing the catheter lock using conventional medical syringes. This is because the gel must be "solid enough" to be reliably retained in the tip of the catheter when the catheter is disposed in the pulsating vascular system of the patient, yet "fluid enough" to be instilled, and withdrawn, using a conventional medical syringe. This is not possible unless the gel is thixotropic. Luissi, Wokalek, Young and Pfirrmann all fail to disclose a thixotropic gel, thus, these references are fatally flawed.

In addition to the foregoing, some further individual deficiencies of Luissi, Wokalek, Young and Pfirrmann will now be discussed.

Looking first at Luissi, Luissi teaches a process for preparing a solid, hydrophilic polymer which swells when mixed with water. As noted above, Luissi does not teach a thixotropic gel. Furthermore, Applicant does not believe that the hydrophilic polymer of Luissi is capable of being instilled into a hemodialysis catheter with a conventional medical syringe. However, for the sake of argument, if the hydrophilic polymer of Luissi were introduced into a hemodialysis catheter, it is believed that the hydrophilic polymer would swell as it absorbed the water which is contained within the blood disposed in the catheter. This swelling would render the catheter unusable and/or cause the hydrophilic polymer to flow out of the catheter and into the bloodstream - both of which would be hazardous to the health of the patient. Thus, Applicant does not believe that the hydrophilic polymer of Luissi discloses the thixotropic gel called for in claim 1.

Wokalek teaches an acoustic coupling medium for transmitting ultrasound during ultrasonic visualization of the human body. The Wokalek medium comprises a sheet of hydrogel containing over 90% water and agar. Wokalek does not describe the mechanical properties of the hydrogel in terms of yield strength and viscosity. However, the fact that Wokalek describes the hydrogel

as a uniform, parallel-sided sheet with a thickness in the range of 3 mm to 25 mm suggests that the hydrogel has a rather high yield strength and, if flowing, a high viscosity. Accordingly, Applicant does not believe that Wokalek teaches the thixotropic gel called for in claim 1.

Young teaches an adhesive patch for the delivery of topical agents to the skin which comprises a hydrogel matrix having adhesive properties, a skin conditioner and a penetration enhancer. Applicant does not believe that Young teaches the thixotropic gel which is called for in claim 1.

Pfirrman teaches a method and composition for combating dentoalveolar infections. The method includes the administration of methylol-transfer agents (i.e., taurolidine and/or taurulam) at an affected area in a patient. In one embodiment, the composition comprises, among other things, taurolidine, hydroxycellulose, gluside and polysorbates. Pfirrmann also teaches that the composition is a liquid gel. Pfirrmann does not describe the rheologic properties of the composition. However, the term "liquid gel" suggests that it is a gel with a high viscosity. This high viscosity gel may be beneficial for use as a dentoalveolar gel since it does not need to be withdrawn once it has been applied to the affected area (e.g., the root canal),

however, the high viscosity of the gel would render it undesirable for use as a catheter lock solution. This is because the high viscosity gel could not be easiliy removed from the hemodialysis catheter using a syringe. Thus, Pfirrmann does not teach the thixotropic gel which is called for in claim 1.

Accordingly, for the reasons discussed above, Luissi, Wokalek, Young and Pfirrmann all fail to teach or suggest a thixotropic gel which has the characteristics called for in claim 1.

Applicant does not believe that the deficiencies of Luissi, Wokalek, Young and Pfirrmann are remedied by Marchant.

Marchant teaches a bioadhesive polymer composition. It is believed that the Marchant composition (see, for example, the two independent claims 1 and 23) is a cross-linked ionic polymer or salt thereof substantially free of soluble polymer (or having a reduced concentration of soluble polymer) and having at least one of the following features when in deionized water at a concentration of 0.5 wt%: (i) a yield stress of between about 10 and about 200 Pa; (ii) a Brookfield viscosity of between 2,000 and 150,000 mPa S; and (iii) a microviscosity value of between 0.01 and about 25.0 Pa S. Even at the lowest viscosity, Marchant is believed to be too viscous for use as a syringe-delivered

catheter lock. This is because the catheter lock solution (with a typical volume of 1.5 to 3 mL) must be rapidly instilled into, or withdrawn from, the hemodialysis catheter using a syringe. The typical injection time is about 2 seconds. While an injection time of greater than 2 seconds might be acceptable, it would not be acceptable if it were to exceed about 10 seconds, since then medical personnel might conclude that the catheter is clotted. Thus, approximately 2 mL of catheter lock solution must be injectable within no more than 10 seconds, which is a flow rate of 12 mL/min. Employing the Hagen-Poiseuille equation indicates that the pressure required to achieve this flow rate is approximately 2000 mmHg. However, the maximum pressure which can be achieved with a syringe is approximately 750 mmHg (i.e., a vacuum). Thus, Marchant fails to teach or suggest a thixotropic gel which has the characteristics called for in claim 1.

In addition to the foregoing, Marchant discloses a bioadhesive polymer composition. While the adhesive characteristics of the Marchant composition may be highly desirable for Marchant's intended applications, they make it totally impractical to use the Marchant composition in a hemodialysis catheter - it could inhibit catheter instillation and removal and, perhaps even more significantly, it could block

a blood vessel (i.e., cause a stroke) in the event that the composition should become free in the bloodstream. Thus, Marchant is not believed to disclose or render obvious the claimed invention.

On account of the foregoing, Applicant submits that claims 1, 3-7 and 11-15 and 19 are in condition for allowance. Early and favorable reconsideration is therefore respectfully requested.

In the event that any additional fees may be required in this matter, please charge the same, or credit any overpayment, to Deposit Account No. 16-0221.

Thank you.

Respectfully submitted,

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